

Lamisil

Terbinafine Hydrochloride 1% Cream

Read all of this leaflet carefully before you start using this medicine, because it contains important information for you.

Always use this medicine exactly as described in this leaflet, or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects listed or not listed in this leaflet.
- You must talk to a doctor, if you do not feel better or if you feel worse.

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1. What Lamisil Cream contains

1g of Lamisil Cream contains 10 mg Terbinafine hydrochloride (active substance) equivalent to 8.8 mg Terbinafine base
Excipients: Purified water, Sodium hydroxide, Benzyl alcohol, Sorbitan stearate, Cetyl palmitate, Cetyl alcohol, Stearyl alcohol, Polysorbate 60, Isopropyl myristate.

2. What Lamisil Cream is and what it is used for

Lamisil Cream is intended for the treatment of skin fungal infections such as Athlete's foot (Tinea pedis).

It is also used to treat a skin yeast infection called Pityriasis (Tinea) versicolor.

Additionally, it can treat skin fungal infections caused by yeast fungi, mainly those of the species *Candida* (e.g. *Candida albicans*).

3. What you need to know before using Lamisil Cream

a. Do not use Lamisil Cream in cases of:

Hypersensitivity to Terbinafine HCL or any one of the excipients contained in Lamisil Cream.

b. Warnings and precautions

Lamisil Cream is intended for external use only.

Avoid contact with the eyes.

Lamisil Cream should be used with caution with skin lesions, since the alcohol may cause irritations.

Lamisil Cream contains cetyl- and stearyl-alcohol which may trigger local skin reactions (e.g. contact dermatitis).

Keep out of sight and reach of children.

c. Pregnancy and Breastfeeding

Pregnancy

There are no controlled studies in pregnant women.

Reproduction studies in animals have shown no risks to the fetus.

Do not use Lamisil Cream during pregnancy, unless it is clearly required.

Breastfeeding

Terbinafine is excreted in small quantities in breast milk. It

is not known whether this small amount in the breast milk can have negative effects on the child. Lamisil Cream

should not be used by women who are breastfeeding.

Infants must not come into contact with treated skin areas.

d. Driving and using machines

No corresponding studies were conducted.

4. How to use Lamisil Cream

For adults and children above 12 years: Before applying Lamisil Cream, carefully wash the affected area with a cotton wool pad and warm water and then dry carefully.

Apply Lamisil Cream to the affected area and surrounding area. Rub in gently to ensure absorption.

In case of intertriginous infections (Sub-mammary, Interdigital, Intergluteal, Inguinal), a gauze strip may be used after applying Lamisil Cream, especially overnight.

Duration of normal treatment

For adults and children above 12 years:

Athlete's foot, superficial skin disorders: 1 time daily for 1 week.

Athlete's foot of the "moccasin type" (athlete's foot on the soles and edges of the feet): 2 times daily for 2 weeks

Fungal infections caused by yeast: 1 to 2 times daily for 1 week

Pityriasis versicolor: 1 to 2 times daily for 2 weeks

Relief of clinical symptoms usually occurs within a few days. Irregular use or premature discontinuation of treatment carries the risk of recurrence.

If there are no signs of improvement after 1 week, patients should see a doctor.

Special dosage recommendations:

Elderly patients

There is no evidence to suggest that elderly patients require different dosages or experience side effects different to those of younger patients.

Children

The use of Lamisil Cream in children less than 12 years is not recommended, due to limited clinical data.

5. Possible side effects of Lamisil Cream

Like all medicines, Lamisil Cream can cause side effects, although not everybody gets them. Local symptoms such as pruritus, skin scaling, pain or irritation, Pigmentation disorders, burning sensations, erythema or scabs may occur at the application site. These harmless symptoms must be differentiated from hypersensitivity reactions, including skin rash, which were reported in individual cases and require immediate termination of treatment. Eye irritation may occur after accidental contact with the eyes.

The underlying fungal infection may worsen in rare cases.

Side effects are listed below by system class and frequency.

Frequency statements are defined as follows: Very common ($\geq 1/10$), Common ($\geq 1/100$, $< 1/10$), Occasionally ($\geq 1/1,000$, $< 1/100$), Rare ($\geq 1/10,000$, $< 1/1,000$), Very rare ($< 1/10,000$).

Within each frequency grouping, side effects are presented in order of decreasing seriousness.

Immune system

The following hypersensitivity reactions were observed:

Very rare: Urticaria

Individual case: Angioedema, Anaphylactic shock

Eyes

Rare: Irritation

Skin

Common: Skin scaling, Pruritus

Occasionally: Skin lesions, Scabs, Skin changes, Pigmentation disorders, Erythema, Burning sensation

Rare: Dry skin, Contact dermatitis, Eczema

Very rare: Skin rash or papules

General disorders

Uncommon: Pain or irritation at the application site

Rare: Worsening of the underlying illness

If any other side effects that are not described in this leaflet occur, you should immediately stop the treatment and inform your doctor or pharmacist.

Interactions

No drug interactions are known with the topical forms of Terbinafine.

6. Overdose

The low systemic absorption of topical terbinafine renders overdosage extremely unlikely. Accidental ingestion of, for example, 2 tubes of Lamisil Cream, containing 300 mg terbinafine hydrochloride, is comparable to the ingestion of a 250 mg Lamisil Tablet (corresponding to the adult oral unit dose). If a larger quantity of topical Lamisil Cream is inadvertently ingested, adverse effects similar to those observed with an overdosage of Lamisil Tablets are to be expected, such as headaches, nausea, epigastric pain and dizziness.

Treatment in case of overdose:

If accidentally ingested, the recommended treatment of overdosage consists of eliminating the medicinal product by the administration of activated charcoal and giving symptomatic supportive therapy, if needed.

7. How to store Lamisil Cream

Medicines must be kept out of sight and reach of children.

Lamisil Cream: Do not store above 30°C. The medicine may not be used beyond the date printed on the package with the indication <EXP>. For more comprehensive information, consult your doctor or pharmacist who have more details intended for representatives of the medical profession.

8. Contents of the pack and other information

15g cream

Manufactured by: GSK Consumer Healthcare SA, Nyon, Switzerland.

MAH: GSK Consumer Healthcare Schweiz AG, Switzerland.

INFORMATION UPDATED

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(THIS IS A MEDICAMENT)

– Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.

The instructions of the pharmacist who sold the medication.

– Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medication.

– The doctor and the pharmacist are experts in medicine, its benefits and risks.

– Do not by yourself interrupt the period of treatment prescribed for you.

– Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Council of Arab Health Ministers

Union of Arab Pharmacists